WE CLAIM:

1. A pharmaceutical composition for oral administration to a mammalian subject, comprising:

a) a taxane or taxane derivative as active ingredient;

b) a vehicle comprising at least 30% by weight of a carrier for the taxane, said carrier having an HLB value at least about 10.

2. A composition according to claim 1 wherein said carrier includes at least one non-ionic surfactant or emulsifier.

3. A composition according to claim 2 wherein said surfactant or emulsifier is selected from the group consisting of Vitamin E TPGS, saturated polyglycolyzed glycerides, modified castor oils, polyoxyethylated stearate esters, polyoxyethylated sorbitan esters, polyoxyethylated fatty ethers, modified almond and corn oil glycerides sorbitan diisostearate esters, polyoxyethylated hydroxystearates, and β-cyclodextrin.

4. A composition according to claim 3 wherein said saturated polyglycolized glycerides include glycerides of C_8 - C_{18} fatty acids.

5. A composition according to claim 3 wherein said modified castor oils are polyoxyethylated or hydrogenated castor oils.

6. A composition according to claim 3 wherein said polyoxyethylated fatty ethers are stearyl or oleyl ethers.

7. A composition according to claim 3 wherein said modified almond and corn oil glycerides comprise polyethylene glycol almond or corn oil glycerides.

8. A composition according to claim 1 wherein the vehicle comprises about 30 - 90% by weight of the carrier.

9. A composition according to claim 1 wherein the taxane is dissolved or dispersed in the vehicle.

10. A composition according to claim 1 wherein the concentration of the taxane in the vehicle is about 2 - 500 mg/ml or mg/g.

11. A composition according to claim 10 wherein the concentration of the taxane in the vehicle is about 2 - 50 mg/ml or mg/g.

12. A composition according to claim 1 wherein the vehicle additionally comprises about 0 - 70% by weight of a co-solubilizer which reduces the viscosity of the vehicle.

13. A composition according to claim 12 wherein the co-solubilizer is capable of solubilizing at least about 25 mg/ml of the taxane at about 20-25°C.

14. A composition according to claim 12 wherein the vehicle comprises about 10 - 50% by weight of the co-solubilizer.

15. A composition according to claim 12 wherein the co-solubilizer is selected from the group consisting of N-methyl-2-pyrrolidone, glycerol or propylene glycol esters of caprylic and capric acids, polyoxyethylated hydroxystearates, polyoxyethylated sorbitan esters, polyethylene glycol esters of caprylic and capric acids, modified castor oils, vegetable oils, such as olive oil, saturated polyglycolyzed glycerides, citrate esters, propylene glycol, ethanol, water and lower molecular weight polyethylene glycols.

16. A composition according to claim 15 wherein said modified castor oils comprise polyoxyethylated or hydrogenated castor oils.

17. A composition according to claim 15 wherein said vegetable oils comprise olive oil.

18. A composition according to claim 15 wherein said saturated polyglycolyzed glycerides comprise glycerides of C_8 - C_{18} fatty acids.

19. A composition according to claim 15 wherein said citrate esters comprise tributyl citrate, triethyl citrate or acetyl triethyl citrate.

20. A composition according to claim 15 wherein said lower molecular weight polyethylene glycols comprise PEG 200 or PEG 400.

21. A composition according to claim 3 wherein the carrier comprises Vitamin E TPGS.

22. A composition according to claim 4 wherein the carrier comprises saturated polyglycolyzed glycerides of C_8 - C_{18} fatty acids.

23. A composition according to claim 18 wherein the co-solubilizer comprises saturated polyglycolyzed glycerides of C_8 - C_{18} fatty acids.

24. A composition according to claim 3 wherein the carrier comprises polyoxyethylated stearate esters.

25. A composition according to claim 15 wherein the co-solubilizer comprises N-methyl-2-pyrrolidone.

26. A composition according to claim 15 wherein the co-solubilizer comprises ethanol.

27. A composition according to claim 1 which, when ingested orally by a mammal one hour after ingestion of an effective oral dose of an oral bioavailability enhancing agent, provides absorption of the taxane active ingredient from the mammal's

gastrointestinal tract into the bloodstream at a level which is at least 15% of the level of absorption achieved when the same amount of the taxane active ingredient is administered to the mammal by intravenous injection in a pharmaceutically acceptable intravenous vehicle.

~~28~~ 27. A composition according to claim ~~27~~ 26 wherein said bioavailability enhancing agent is a cyclosporin.

~~29~~ 28. A composition according to claim ~~28~~ 27 wherein said cyclosporin is cyclosporin A.

~~30~~ 29. A composition according to claim 1 wherein said taxane is paclitaxel or docetaxel.

~~31~~ 30. A composition according to claim ~~30~~ 29 wherein said taxane is paclitaxel.

~~32~~ 31. An oral pharmaceutical dosage form comprising a pharmaceutical composition according to claim 1 .

~~33~~ 32. A dosage form according to claim ~~32~~ 31 which comprises a liquid preparation.

~~34~~ 33. A dosage form according to claim ~~32~~ 31 wherein the pharmaceutical composition is encapsulated in a soft or hard gelatin capsule.

~~35~~ 34. A dosage form according to claim ~~32~~ 31 which additionally comprises pharmaceutical excipients, diluents, sweeteners, flavoring agents or coloring agents.

~~36~~ 35. A dosage form according to claim ~~32~~ 31 wherein the taxane is paclitaxel or docetaxel.

~~37~~ 36. A dosage form according to claim ~~36~~ 35 wherein the taxane is paclitaxel.

38. A dosage form according to claim 32 which contains about 20 - 1000 mg/m^2 of the taxane based on the body surface area of the mammalian subject.

39. A dosage form according to claim 38 which contains about 50 - 200 mg/m^2 of the taxane based on the body surface area of the mammalian subject.

40. A dosage form according to claim 32 which contains about 0.5 - 30 mg/kg of the taxane based on the weight of the mammalian subject.

41. A dosage form according to claim 40 which contains about 2 - 6 mg/kg of the taxane based on the weight of the mammalian subject.

42. A two-part medicament for oral administration to a mammalian subject, the first part of said medicament comprising a taxane or taxane derivative as active ingredient in a solubilizing vehicle for said taxane, and the second part of said medicament comprising at least 30% by weight of a carrier for the taxane, said carrier having an HLB value at least about 10.

43. A two-part medicament according to claim 42 wherein the solubilizing vehicle is capable of solubilizing at least about 25 mg/ml of the taxane at about 20-25°C.

44. A two-part medicament according to claim 42 wherein the solubilizing vehicle comprises water, ethanol or a polyoxyethylated or hydrogenated castor oil.

45. A two-part medicament according to claim 42 wherein the solubilizing vehicle comprises sweetening, flavoring or coloring agents.

46. A two-part medicament according to claim 42 wherein the solubilizing vehicle contains about 2 - 500 mg/ml or mg/g of the taxane.

47. A two-part medicament according to claim 46 wherein the solubilizing vehicle contains about 2 - 50 mg/ml or mg/g of the taxane.

48. A two-part medicament according to claim 42 wherein the carrier includes at least one non-ionic surfactant or emulsifier.

49. A two-part medicament according to claim 48 wherein the carrier includes at least one surfactant or emulsifier selected from the group consisting of Vitamin E TPGS, saturated polyglycolyzed glycerides, modified castor oils, polyoxyethylated stearate esters, polyoxyethylated sorbitan esters, polyoxyethylated fatty ethers, modified almond and corn oil glycerides sorbitan diisostearate esters, polyoxyethylated hydroxystearates, and β-cyclodextrin.

50. A two-part medicament according to claim 42 wherein the second part of the medicament comprises about 30-240 ml of fluid.

51. A two-part medicament according to claim 42 wherein the taxane is paclitaxel or docetaxel.

52. A two-part medicament according to claim 51 wherein the taxane is paclitaxel.

53. A method of treating a mammalian subject suffering from a taxane-responsive disease condition comprising the oral administration to the subject of a pharmaceutical composition comprising:

a) a taxane or taxane derivative as active ingredient;

b) a vehicle comprising at least 30% by weight of a carrier for the taxane, said carrier having an HLB value at least about 10.

54. A method according to claim 53 wherein said carrier includes at least one non-ionic surfactant or emulsifier.

55. A method according to claim 54 wherein said surfactant or emulsifier is selected from the group consisting of Vitamin E TPGS, saturated polyglycolyzed glycerides, modified castor oils, polyoxyethylated stearate esters, polyoxyethylated sorbitan esters, polyoxyethylated fatty ethers, modified almond and corn oil glycerides sorbitan diisostearate esters, polyoxyethylated hydroxystearates, and β-cyclodextrin.

56. A method according to claim 55 wherein said saturated polyglycolized glycerides include glycerides of C_8 - C_{18} fatty acids.

57. A method according to claim 55 wherein said modified castor oils are polyoxyethylated or hydrogenated castor oils.

58. A method according to claim 55 wherein said polyoxyethylated fatty ethers are stearyl or oleyl ethers.

59. A method according to claim 55 wherein said modified almond and corn oil glycerides comprise polyethylene glycol almond or corn oil glycerides.

60. A method according to claim 53 wherein the vehicle comprises about 30 - 90% by weight of the carrier.

61. A method according to claim 53 wherein the taxane is dissolved or dispersed in the vehicle.

62. A method according to claim 53 wherein the concentration of the taxane in the vehicle is about 2 - 500 mg/ml or mg/g.

63. A method according to claim 62 wherein the concentration of the taxane in the vehicle is about 2 - 50 mg/ml or mg/g.

64. A method according to claim 53 wherein the vehicle additionally comprises about 0 - 70% by weight of a co-solubilizer which reduces the viscosity of the carrier.

65. A method according to claim 64 wherein the co-solubilizer is capable of solubilizing at least about 25 mg/ml of the taxane at about 20-25°C.

66. A method according to claim 64 wherein the vehicle comprises about 10 - 50% by weight of the co-solubilizer.

67. A method according to claim 64 wherein the co-solubilizer is selected from the group consisting of N-methyl-2-pyrrolidone, glycerol or propylene glycol esters of caprylic and capric acids, polyoxyethylated hydroxystearates, polyoxyethylated sorbitan esters, polyethylene glycol esters of caprylic and capric acids, modified castor oils, vegetable oils, such as olive oil, saturated polyglycolyzed glycerides, citrate esters, propylene glycol, ethanol, water and lower molecular weight polyethylene glycols.

68. A method according to claim 67 wherein said modified castor oils comprise polyoxyethylated or hydrogenated castor oils.

69. A method according to claim 67 wherein said vegetable oils comprise olive oil.

70. A method according to claim 67 wherein said saturated polyglycolyzed glycerides comprise glycerides of C_8 - C_{18} fatty acids.

71. A method according to claim 67 wherein said citrate esters comprise tributyl citrate, triethyl citrate or acetyl triethyl citrate.

72. A method according to claim 67 wherein said lower molecular weight polyethylene glycols comprise PEG 200 or PEG 400.

73. A method according to claim 55 wherein the carrier comprises Vitamin E TPGS.

74. A method according to claim 56 wherein the carrier comprises saturated polyglycolyzed glycerides of C_8 - C_{18} fatty acids.

75. A method according to claim 70 wherein the co-solubilizer comprises saturated polyglycolyzed glycerides of C_8 - C_{18} fatty acids.

76. A method according to claim 55 wherein the carrier comprises polyoxyethylated stearate esters.

77. A method according to claim 67 wherein the co-solubilizer comprises N-methyl-2-pyrrolidone.

78. A method according to claim 67 wherein the co-solubilizer comprises ethanol.

79. A method according to claim 53 wherein the composition, when ingested orally by a mammal one hour after ingestion of an effective oral dose of an oral bioavailability enhancing agent, provides absorption of the taxane active ingredient from the mammal's gastrointestinal tract into the bloodstream at a level which is at least 15% of the level of absorption achieved when the same amount of the taxane active ingredient is administered to the mammal by intravenous injection in a pharmaceutically acceptable intravenous vehicle.

80. A method according to claim 79 wherein said bioavailability enhancing agent is a cyclosporin.

81. A method according to claim 80 wherein said cyclosporin is cyclosporin A.

82. A method according to claim 53 wherein said taxane is paclitaxel or docetaxel.

83. A method according to claim 82 wherein said taxane is paclitaxel.

84. A method according to claim 53 wherein said pharmaceutical composition is administered to the subject in an oral pharmaceutical dosage form.

85. A method according to claim 84 wherein the dosage form comprises a liquid preparation.

86. A method according to claim 84 wherein the pharmaceutical composition is encapsulated in a soft or hard gelatin capsule.

87. A method according to claim 84 wherein the dosage form additionally comprises pharmaceutical excipients, diluents, sweeteners, flavoring agents or coloring agents.

88. A method according to claim 84 wherein the taxane is paclitaxel or docetaxel.

89. A method according to claim 88 wherein the taxane is paclitaxel.

90. A method according to claim 84 wherein the dosage form contains about 20 - 1000 mg/m^2 of the taxane based on the body surface area of the mammalian subject.

91. A method according to claim 90 wherein the dosage form contains about 50 - 200 mg/m^2 of the taxane based on the body surface area of the mammalian subject.

92. A method according to claim 84 wherein the dosage form contains about 0.5 - 30 mg/kg of the taxane based on the weight of the mammalian subject.

93. A method according to claim 92 wherein the dosage form contains about 2 - 6 mg/kg of the taxane based on the weight of the mammalian subject.

94. A method of treating a mammalian subject suffering from a taxane-responsive disease condition comprising the oral administration to the subject of a two-part medicament, the first part of said medicament comprising a taxane or taxane derivative as active ingredient in a solubilizing vehicle for said taxane and the second part of said medicament comprising at least 30% by weight of a carrier for the taxane, said carrier having an HLB value at least about 10.

95. A method according to claim 94 wherein the solubilizing vehicle is capable of solubilizing at least about 25 mg/ml of the taxane at about 20-25°C.

96. A method according to claim 94 wherein the solubilizing vehicle comprises water, ethanol or a polyoxyethylated or hydrogenated castor oil.

97. A method according to claim 94 wherein the solubilizing vehicle comprises sweetening, flavoring or coloring agents.

98. A method according to claim 94 wherein the solubilizing vehicle contains about 2 - 500 mg/ml or mg/g of the taxane.

B

99. A method according to claim 98 wherein the solubilizing vehicle contains about 2 - 50 mg/ml or mg/g of the taxane.

100. A method according to claim 94 wherein the carrier includes at least one non-ionic surfactant or emulsifier.

101. A method according to claim 94 wherein the carrier includes at least one surfactant or emulsifier selected from the group consisting of Vitamin E TPGS, saturated polyglycolyzed glycerides, modified castor oils, polyoxyethylated stearate esters, polyoxyethylated sorbitan esters, polyoxyethylated fatty ethers, modified almond and

corn oil glycerides sorbitan diisostearate esters, polyoxyethylated hydroxystearates, and β-cyclodextrin.

102. A method according to claim 94 wherein the second part of the composition comprises about 30-240 ml of fluid.

103. A method according to claim 94 wherein the taxane is paclitaxel or docetaxel.

104. A method according to claim 103 wherein the taxane is paclitaxel.

105. A method according to claim 53 which additionally comprises the co-administration to the subject of an effective bioavailability-enhancing amount of an oral bioavailability-enhancing agent.

106. A method according to claim 105 wherein said effective amount of the enhancing agent is about 0.1 - 20 mg/kg based on the weight of the mammalian subject.

107. A method according to claim 105 wherein the enhancing agent is administered either

a) about 0.5-72 hrs. before,

b) less than 0.5 hr. before, together with or less than 0.5 hr. after, or

c) both about 0.5-72 hrs. before and again less than 0.5 hr. before, together with or less than 0.5 hr. after,

the administration of the taxane.

108. A method according to claim 107 wherein said enhancing agent is administered one hour before the administration of the taxane-containing pharmaceutical composition.

109. A method according to claim 105 wherein the enhancing agent is selected from the group consisting of cyclosporins A through Z, (Me-Ile-4)-cyclosporin, dihydro cyclosporin A, dihydro cyclosporin C and acetyl cyclosporin A .

110. A method according to claim 109 wherein the enhancing agent is selected from the group consisting of cyclosporin A, cyclosporin C, cyclosporin D, cyclosporin F, dihydro cyclosporin A, dihydro cyclosporin C and acetyl cyclosporin A.

111. A method according to claim 110 wherein the enhancing agent is cyclosporin A.

112. A method according to claims 53 or 105 wherein said disease condition is selected from the group consisting of cancers, tumors, malignancies, uncontrolled tissue or cellular proliferation secondary to tissue injury, polycystic kidney disease and malaria.

113. A method according to claim 112 wherein said disease is a cancer selected from the group consisting of hepatocellular carcinoma, liver metastases, cancers of the gastrointestinal tract, pancreas, prostate and lung, and Kaposi's sarcoma.

114. A method according to claim 105 wherein the taxane and the enhancing agent are administered together in a combination oral dosage form.

115. A method according to claim 105 wherein the taxane is paclitaxel or docetaxel.

116. A method according to claim 115 wherein the taxane is paclitaxel.

117. A method according to claims 53, 84, 94 or 105 wherein the mammalian subject is a human being.

add A6 B1